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Technical Report

Economic study: a cost-effectiveness analysis of an intraoperative compared with a preoperative image-guided system in lumbar pedicle screw fixation in patients with degenerative spondylolisthesis

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Abstract

BACKGROUND CONTEXT: In spinal surgery, newly developed technology seems to play a key role, especially with the use of computer-assisted image-guided navigation, giving excellent results. However, these tools are expensive and may not be affordable for many facilities.

PURPOSE: To compare the cost-effectiveness of preoperative versus intraoperative CT (computed tomography) guidance in spinal surgery.

STUDY DESIGN: A retrospective economic study.

METHODS: A cost-effectiveness study was performed analyzing the overall costs of a population of patients operated on for lumbar degenerative spondylolisthesis using an image-guided system (IGS) based on a CT scan. The population was divided into two groups according to the type of CT data set acquisition adopted: Group I (IGS based on a preoperative spiral CT scan), Group II (IGS based on an intraoperative CT scan—O-Arm system). The costs associated with each procedure were assessed through a process analysis, where clinical procedures were broken down into single phases and the related costs from each phase were evaluated. No benefits in any form have been or will be received from commercial parties directly or indirectly related to the subject of this article.

RESULTS: Four hundred ninety-nine patients met the criteria for this study. In total, 2,542 screws were inserted with IGS. Baseline data were similar for the two groups, as were hospitalization and complications. The surgical time was 119±43 minutes in Group I and 92±31 minutes in Group II. The full cost of the two procedures was analyzed: the mean cost, using the O-Arm system (Group II), was found to be €255.83 (3.80%) less than the cost of Group I. Moreover, the O-Arm system was also used in other surgical procedures as an intraoperative control, thus reducing the final costs of radiologic examinations (a reduction of around 550 CT scans/year).

CONCLUSIONS: In conclusion, the authors of the study are of the opinion that the surgical procedure of pedicle screw fixation, using a CT-based computer-guidance system with support of the O-Arm system, allows a shortening of procedure time that might improve the clinical result.

FDA device/drug status: Not approved for this indication.

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However, the present study failed to determine a clear cost-effectiveness with respect to other CT-based IGS.

Keywords: Navigation system; Economic analysis; Costs; Imaging; Spine

Introduction

In recent years, the increasing use of technology has changed many surgical procedures, reducing risks and improving clinical results. Newly developed technologies play a key role in spinal surgery and many results have now been reported in literature. Different tools, such as electrical conductivity measuring devices [1] or different types of computer-assisted image-guided navigation [2–4] have been described and show promising results. In particular, recently introduced systems, such as fluoroscopy-based image guidance (“virtual fluoroscopy”) and computed tomography (CT)-based computer guidance, have considerably reduced the risk of pedicle screw misplacement, showing overall perforation rates ranging from 14.3% to 4.8% [3,5] and represent, in an ever increasing number of departments, the gold standard for instrumented spinal surgery. However, despite these results, a cost-effectiveness analysis is needed. To date, there are no economic studies to show if the acquisition of this technology may or may not be sustainable from the hospitals’ point of view besides the useful role it plays in daily practice. The image-guided system (IGS), based on a navigation system and eventually with an intraoperative CT scan, has a high purchasing cost, from €90,000 to €550,000. Although its use may be justified in specialized spinal units, this kind of investment is often not considered an affordable option for many facilities.

Therefore, the purpose of the present study was to validate the methodology of a cost-effectiveness study comparing a computer-guidance system based on a preoperative versus intraoperative CT scan acquisition (O-Arm system, Medtronic, Minneapolis, MN, USA), and to analyze its economic impact on daily practice.

Material and methods

A retrospective cost-effectiveness study [6] was conducted to analyze the overall costs of a population of patients admitted to the Department of Neurosurgery. The patients enrolled in this study had been admitted with a diagnosis of degenerative spondylolisthesis and had undergone a surgical procedure of lumbar pedicle screw fixation using a CT-based computer-guidance system. The navigation system adopted and used in all cases was the StealthStation Treon (Medtronic, Minneapolis, MN, USA). The patients were divided into two groups, according to the type of CT data set used for the navigation system and according to the year of the procedure: Group I (IGS based on a preoperative spiral CT scan, 2008) and Group II (IGS based on an intraoperative CT scan, 2010). All surgical procedures were performed by four neurosurgeons, well experienced in spinal surgery and navigation systems (routinely used in our Department in spine surgery since 2003). The study excluded data concerning the year 2009 in which the O-Arm system was operational, in order to reduce any possible bias because of the learning curve of the new device.

The radiologic protocol for the preoperative (Somatom Volume Zoom, Siemens, Munich, Germany) and intraoperative (O-Arm Imaging system) CT scans was the same as described by the authors in a previous study [5].

The economic evaluation was conducted from a hospital perspective. Costs of the two procedures were measured and valued using an activity-based costing approach [7] (microcosting approach). The procedures were divided into single phases and the costs of each phase were measured and valued. All costs incurred by the hospital, including human resources, operating room (OR) specific machinery (ie, navigation system, O-Arm system, fluoroscopy: considering an 8-year amortization), surgical instruments, consumption materials, drugs, prostheses, and overhead costs, were collected from the hospital’s accounting service. The evaluation took into consideration all of the phases, from preadmission testing to discharge of a typical mean pathway of a standard patient who did not present complications. The costs (inclusive of value added tax) data refer to 2010, the material and services consumption levels refer to the clinical practice of years 2008 and 2010, and the cost data were collected from the hospital accounting service referring to 2010 levels.

The effectiveness assessment concerning the two procedures looked at the accuracy of pedicle screw placement. In particular, considered “effective” were the screws graded according to the Laine et al. [2] classification as 0, I, and II (maximal cortical violation <4 mm). In fact, screws graded as III or IV are considered potentially dangerous for the nerve root and vascular structures [8], which may lead to secondary interventions. It should be noted that the Lombardy region healthcare service does not reimburse the hospital for a second surgical intervention for the same diagnosis (such as the repositioning of a misplaced screw) within 30 days from the initial intervention.

Statistical analysis was conducted by means of Student t test for interval data (economic values, age, time, and number of screws placed) and by means of a chi-square test for nominal data (gender).

No benefits in any form have been received or will be received from commercial parties directly or indirectly related to the subject of this article.

Results

Of a total of 3,058 surgical procedures performed in the Department in 2008 and 2010 (1,451 performed in 2008 and 1,607 in 2010), an IGS was used 945 times (30.9%): 370 times (39.1%) in 2008 and 575 (60.9%) in 2010. The population of the study comprised 499 patients, who underwent surgery for degenerative spondylolisthesis with a lumbar spinal arthrodesis by pedicle screw fixation using an IGS (198 in Group I and 301 in Group II). The subpopulation of patients who had previously been operated on the same levels of the actual surgery was 51 cases (25%) in Group I and 98 (32%) in Group II, without a statistically significant difference (p value, .104). In total, there were 266 females and 233 males (102 females, 51.5%, and 96 males, 48.5%, in Group I and 164 females, 54.5%, and 137 males, 45.5%, in Group II). The mean age of the patients was 67.5±13 (range, 45–77 years) years in Group I, and 69.7±14 (range, 43–85 years) years in Group II (Table 1).

All patients underwent a lumbar fixation and decompression surgery for degenerative spondylolisthesis: the length of instrumentation was in 298 cases (59.7%) at one level, in 134 patients (26.9%) at two levels, whereas three- or four-level fixations were necessary in 62 (12.4%) and 5 cases (1.0%), respectively. The distribution through the two groups is detailed in Table 1.

A total of 2,542 titanium pedicle screws (mean, 5.09 screws per patient; range, 4–10) were inserted between L1 and S1: 1,002 screws in Group I (mean, 5.06 per patient) and 1,540 in Group II (mean, 5.12 per patient), without a statistically significant difference. The pedicle screw systems used were Legacy (Medtronic, Minneapolis, MN, USA), Expedium (DePuy Spine, Raynham, MA, USA), and 3Lock (Sintea Plustek Srl, Assago, Italy). The correct diameter of the screw was selected according to the information provided by the CT scan images using the navigation system.

No statistical difference was found between the two groups concerning age, gender, or levels, whereas a statistically significant difference was found between the number of screws per patient (Table 1). The proportion of cases operated on by each individual surgeon is similar between the two groups.

The overall mean operating time was 119±43 (range, 85–165 minutes) minutes in Group I and 92±31 (range, 55–147 minutes) minutes in Group II. Analysis of the two subpopulations in each group revealed that the surgical time in Group I was 98.7±6 (range, 85–112 minutes) minutes for first surgery and 126±15 (range, 96–165 minutes) minutes for reoperation, whereas in Group II it was 83.5±14 (range, 55–147 minutes) minutes and 97.3±7 (range, 91–147 minutes) minutes, respectively, with a statistically significant difference (Table 2).

According to the results presented in a previous study by the authors [5], the mean time used to merge the three-dimensional (3D) reconstruction images of the navigation system with the surgical anatomy (using anatomic landmarks for paired-point matching registration) was 6.5±2.3 (range, 3–9 minutes) minutes in Group I, whereas for Group II, the mean time to acquire the CT scan with the O-Arm and the autotransfer to the navigation system was 1.15±0.35 (range, 0.40–1.55 minutes) minutes. This time was calculated with the sum of the time of CT scanning (around 13 seconds), 3D reconstruction (around 20 seconds), handling of the O-Arm, and of the operating table (performed simultaneously using the automatic position of each device) as well as the draping of the operating fields (and not of the O-Arm).

Table 1
Study sample characteristics

Characteristics	Group I	Group II	p Value
Number of patients	198	301	—
Men (%)	96 (48.5)	137 (45.5)	.515
Mean age (SD) (y)	67.53 (±13)	69.70 (±14)	.239
Levels of pathology (%)			
1 level	121 (61.1)	177 (58.9)	.964
2 levels	51 (25.7)	83 (27.6)	
3 levels	24 (12.1)	38 (12.6)	
4 levels	2 (1.1)	3 (0.9)	
Mean instrumentation (SD)	5.06 (±1.2)	5.12 (±1.0)	.001

SD, standard deviation.

Accordingly, the mean time used to insert the pedicle screws was 28±12 (range, 8–42 minutes) minutes in Group I and 16±10 (range, 6–28 minutes) minutes in Group II. The mean insertion time *per* screw was 3.8 minutes in Group I and 2.9 minutes in Group II (Table 2).

The accuracy of the pedicle screw placement is summarized in Table 3.

Screws classified outright as misplaced were those with a cortex violation of greater than 4 mm (Grade III and IV); potentially dangerous [8]: these data represent the effectiveness of the two procedures. In Group I, eight screws (0.8%) were classified as accidentally misplaced. However, no reoperations were performed to replace these screws; the CT scan control was performed the day after the surgery, the criteria for a reoperation because of a misplaced screw was mostly clinical. In Group II, 13 screws (0.9%) were replaced during the same surgical intervention (where an intraoperative CT scan control was performed) because they were considered potentially dangerous (Table 3); as the screws were replaced, a new CT scan control with the O-Arm system was performed and all the screws were graded "0". The positioning error of these screws was because of modification of the position of the passive frame during surgery. Analyzing the effectiveness values (screws graded as III or IV), it is 99.2% in Group I and 100% in Group II. The better result for the O-Arm system is because of the possibility of assessing the positioning of each screw during the intervention and, if necessary, correcting it during the same surgical intervention (Group IIb). The mean

Table 2
Time absorption of different procedure phases

Characteristics	Group I	CI (95%)	Group II	CI (95%)	p Value
Overall mean time, min (SD)	119 (±43)	112.9–125.1	92 (±31)	88.5–95.5	.110
Surgical mean time (first surgery), min (SD)	98.7 (±6)	97.9–99.5	83.5 (±14)	81.9–85.1	.000
Surgical mean time (reoperation), min (SD)	126 (±15)	123.9–128.1	97.3 (±7)	96.5–98.1	.000
Mean time to acquire CT information, min (SD)	6.5 (±2.3)	6.2–6.8	1.15 (±0.35)	1.0–1.3	.000
Mean pedicle screws insertion, min (SD)	28 (±12)	26.3–29.7	16 (±10)	14.2–17.8	.000

CI, confidence interval; CT, computed tomography; SD, standard deviation.

hospitalization was 5.9 days in Group I and 5.7 days in Group II. A blood transfusion was necessary for 22 patients (11.1%) requiring a total of 38 blood bags in Group I and for 25 patients (8.3%) requiring a total of 41 blood bags in Group II.

One patient (0.5%) in Group I presented a postoperative wound infection that needed a second recovery, treated with antibiotic drugs (no surgery was performed); whereas in Group II, two patients (0.7%) presented an infection, one of whom required reintervention for a surgical toilette.

With regard to the economic evaluation, the cost of the procedure using the O-Arm system was calculated to be €6,482 (±425.7), whereas that of the standard IGS procedure was €6,738 (±536.2). The percentage impact of each cost category is presented in Table 4. The difference in terms of total cost is not statistically significant (p value, .468).

The use of the O-Arm led to a saving of 3.8% in comparison with the traditional IGS procedure. The two main differences were the fewer number of radiology examinations needed and the reduced time required to complete the procedure (with consequences on the costs of human resources and anesthesia drugs). For the use of the O-Arm, amortization is ascribed to the machinery.

A sensitivity analysis was performed modifying the surgical intervention time, the necessary time to merge 3D reconstruction and acquire CT on O-Arm, the number of blood transfusions, the number of inpatient days, and the use of a lumbar sacral X-ray substituting CT as a postsurgical diagnostic procedure. The results show minimum and maximum costs of €6,238 and €7,474 in Group I and €6,106 and €7,276 in Group II, respectively.

Table 3
Pedicle screw accuracy evaluated according to Laine et al. [2] classification

Grades	Group I (%)	Group IIa (%)	Total	Group IIb (%)	Total
0	913 (91.1)	1,469 (95.4)	2,382	1,482 (96.2)	2,395
1	59 (5.9)	52 (3.4)	111	52 (3.4)	111
2	22 (2.2)	6 (0.4)	28	6 (0.4)	28
3	7 (0.7)	12 (0.8)	19	0 (0)	7
4	1 (0.1)	1 (0.1)	2	0 (0)	1
Total	1,002	1,540	2,542	1,540	2,542

CT, computed tomography.

Note: Group IIa: results evaluated at first CT scan control performed with O-Arm system; Group IIb: results evaluated with a second CT scan control performed after intraoperative screws replacement.

The cost-effectiveness values of the two procedures show a slightly lower value for the O-Arm (Group II) procedure which, therefore, means a better result. The detailed data are presented in Table 5.

A further sensitivity analysis was performed to test the robustness of the results, considering a variation of costs, as presented before, and a variation of effectiveness of ±1% (not exceeding 100%). Considering a 500 scenarios simulation, in 46.6% of cases, the use of the O-arm resulted in a reduction of costs and an increase in effectiveness; in 9.4% of cases it resulted in an increase of costs and a reduction in effectiveness; in 28.4% of cases it resulted in an increase of costs and effectiveness; and in 15.6% of cases it resulted in a reduction of costs and effectiveness.

Considering radiologic investigations (preoperative, intraoperative, and postintervention), 584 CT were performed in 2008, 1.6 per patient, and 47 CT scans were performed in 2010, 1.1 per patient (0.1 CT per patient was necessary at the Radiology Department, as all the other CT investigations were performed with the O-Arm system).

Discussion

The evolution of IGS in spinal surgery is growing, and new solutions are continuously being proposed and described. Although spinal navigation is a well-established procedure [3,4,9–13], to date few published articles have assessed the clinical effectiveness of the O-Arm system

Table 4
Cost of the procedures (source: reprocessing of study data)

Costs analyzed	Traditional procedure cost (% impact on total cost), €	O-Arm procedure cost (% impact on total cost), €
Human resources	1,562.61 (23.19)	1,470.55 (22.69)
Machineries	42.72 (0.63)	143.74 (2.22)
Surgical instruments	88.90 (1.32)	88.90 (1.37)
Laboratory tests	46.15 (0.68)	46.15 (0.71)
Diagnostic tests	227.62 (3.38)	29.00 (0.45)
Prosthesis	1,726.40 (25.62)	1,726.40 (26.63)
Blood transfusions	140.00 (2.08)	140.00 (2.16)
Consumable materials	1,382.28 (20.52)	1,382.28 (21.33)
Drugs	88.59 (1.31)	76.81 (1.18)
Overheads	1,432.42 (21.26)	1,378.03 (21.26)
Total	6,738	6,482

Table 5
Cost-effectiveness analysis results (source: reprocessing of study data)

Type of IGS	Cost (€) [C]	Effectiveness (%) [E]	Incremental cost [ΔC]	Incremental effectiveness [ΔE]	Cost effectiveness value	ICER [ΔC/ΔE]
Traditional procedure	6,738	99.2	6,738	99.2	6,792	—
O-Arm procedure	6,482	100	−256	0.8	6,482	−31,980

ICER, Incremental Cost Effectiveness Ratio.

[5,14–16]. The clinical and radiologic results of this technology look promising; however, it is necessary to emphasize that the costs of these systems are very high and many facilities cannot afford them. This study analyzed the costs of surgical procedure for instrumented spinal surgery in two different years according to the type of IGS adopted (preoperative vs. intraoperative CT scans performed with O-Arm system).

The present study offers only partial results to the real cost-effectiveness value of the IGS analyzed because of different drawbacks and limitations in the study itself. The main concerns are:

- The study is retrospective. Because of this, many useful data in economic evaluation are lacking;
- Secondly, the authors chose to analyze the data regarding two nonconsecutive years, 2008 and 2010. This choice may be criticized: the so-called ‘‘learning curve cases’’ are known to represent an additional cost in the acquisition of a new device and method, but their impact may be amortized in a major time span. Ideally, to have a correct comparison between the two IGS procedures analyzed in the study, the ‘‘learning curve cases’’ of Group I (referred to year 2003) should have been taken into consideration to be studied and compared. One of the aims of the authors was to try to define a protocol of a highly replicable study, and for this reason they tried to reduce any possible bias between the two procedures. The surgeons involved in this study were all experienced in spinal surgery and IGS procedure (used routinely in our Department since 2003) and hence, the time span of 2 years was supposed to have had a minimal influence concerning the surgical skills and surgical time of the procedure evaluated;
- From 2008 to 2010 because of an increased number of ORs available for the Department, the number of surgeries/year increased leading to a difference in the two samples (198 vs. 301 cases);
- The population analyzed in this study was only composed of patients who were treated surgically for degenerative spondylolisthesis and represents only one of the possible surgical procedures in which the IGS and the O-Arm system may be used. Again the authors preferred to reduce the heterogeneity of the sample of the two periods analyzed and excluded more challenging cases such as deformity, fractures, cervical, and thoracic cases, reducing the bias of the samples.

The results of our study showed a cost difference of 3.8% between the two IGS procedures, without a statistically significant reduction, from the viewpoint of the hospital. However, the use of the O-Arm system seems to suggest an economic advantage, as emerged in calculating the break-even point, when it is used to perform a minimum of 154 surgical interventions per year (considering an 8-year amortization period). A complete evaluation regarding the economic impact of the IGS may be achieved only with a fully comprehensive cost-effectiveness analysis. Moreover, the navigation system and the O-Arm system that allows the possibility of achieving an intraoperative radiologic exam (fluoroscopy or a CT scan) [17], may also be used in different neurosurgical procedures (as stated by the increase of the utilization of this technology in routine daily activity, varying from 39.1% in 2008 to 60.9% in 2010) as well as in other fields (ie, in orthopedics, ear nose and throat surgery, and maxillofacial surgery), thus reducing the financial impact of this technology on the Department.

An additional benefit of using the O-Arm system is the possibility of not needing to perform a CT scan in the presurgical phase and a CT scan or an X-ray in the postsurgical phase. This would positively affect the imaging department by shortening the waiting lists for the performance of CT and/or X-ray examinations. The sensitivity analysis performed showed that avoiding a postoperative CT scan would result in a decrease of €99.31 in the economic result of Group I, not modifying the results of the analysis (considering the lack of statistical significance in the cost difference between the two groups).

The results of this study may be considered in the context of the Department, the hospital, and the regional health-care service to which they refer. It is, therefore, difficult to compare our results with already published cost-effectiveness and cost-utility analyses [18,19] because of the different contexts in which cost data were collected (Italian public funded National Healthcare Service vs. United States private Healthcare Service). Watkins et al. [18] underlined the advantages of the use of IGSs for the placement of pedicle screws in terms of surgical intervention time reduction. In particular the IGSs were considered to be cost-effective when compared with procedures without image guidance in spine practices. However must be noted that the authors analyzed only hospitals with heavy

volumes of challenging cases, that require longer surgical times, also for pedicle screws positioning. Adogwa et al. [19] assessed the cost utility for the revision decompression of neural elements and extension of fusion, obtaining a mean 2-year cost per quality-adjusted life year gain of $62,955.

The methodology used in the study is highly replicable, while results should be contextualized in the department and health care system of reference. The analyses of both groups were conducted within the same context and the analysis of results is, therefore, not affected by the context of reference. The analysis focused on the hospital's point of view; however, further analysis should also take into consideration the societal point of view, that is, loss of productivity. The inclusion of indirect costs would lead to an advantage for the intervention that allows shorter hospitalization times and faster recovery. Therefore, as previously mentioned, an accurate, prospective, cost-effectiveness study is necessary to evaluate the real economic impact on the clinical practice of this technology and whether the costs of such evaluated devices may justify their use in daily practice.

The use of a microcosting approach allowed a precise detection of the resources used to treat the patients in the two groups, other approaches, such as macrocosting, would have led to a mean cost per patient with the risk to underestimate or overestimate the consumption of resources.

Use of IGS in spine surgery implies two other main observations that are difficult to evaluate from an economic point of view, they are ethical consideration and dose exposure.

Concerning ethics, an important effect on patients using an intraoperative image system is the possibility to intraoperatively control the position of the screws and eventually correct those considered incorrect during the same surgical procedure, thus reducing the stress created in having to undergo a second surgical intervention and, in addition, allowing the reduction of any potential medical and legal risks. This procedure may also lead to a reduction in waiting lists. A hospital could benefit from the adoption and use of the O-Arm system by reducing the cost per patient and time for surgical procedure of lumbar pedicle screw fixation, thus leading to a hypothetical increase in productivity of the OR resulting in an increase of revenues.

Another relevant consideration regards radiation exposure. In fact, IGS reduces exposure in the OR as stated by Gebhard et al. [20], especially for the operators. This would be a positive effect from the point of view of public health care, with a potential reduction of malignancy induction. However, definitive results are currently lacking. A different consideration must be carried out for the patient. In fact, the mean radiation exposure for a patient using an IGS based on CT images is higher with respect to standard procedures using fluoroscopy. In particular, when a spiral preoperative CT scan is used, the mean exposure is of 7.27 mSv versus 0.48 mSv of the fluoroscopy [21], whereas with an intraoperative CT scan performed with the O-Arm system, it is of 2.52 mSv.

The results of the present study give partial information to the real cost-effectiveness value of the technology used in spinal surgery. In particular, the O-Arm system in this study presents similar cost-effectiveness when compared with IGS based on preoperative CT scan. However, the highlighted trend suggests that in specialized spinal centers, where more than 150 surgical procedures are performed per year, the O-Arm system could be considered.

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